REMARKS

Claims 1-3, 5-12, 17-19, 21-28, 33-53, 56-58, 63-85, 87, 89-90 and 92 were examined. Claim 63 is amended. Claims 1-3, 5-12, 17-19, 21-28, 33-46, 51-53, 56-58, 63-85, 87, 89-90 and 92-95 remain in the Application.

The Patent Office rejects claims 33-38, 42-43, 45-46, 63, 65 and 92-95 under 35 U.S.C. §102(e). The Patent Office rejects claims 1-3, 5-8, 11-12, 17-19, 21-24 and 27-28 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the following remarks.

A. 35 U.S.C. § 102(e): Rejection of Claims 33-38, 42-43, 45-46, 63, 65 & 92-95

The Patent Office rejects claims 33-38, 42-43, 45-46, 63, 65 and 92-95 under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,692,466 of Chow et al. (Chow).

Independent claim 33 describes an apparatus including an expandable body; at least one delivery cannula coupled to an exterior portion of the expandable body and comprising a plication region defined in response to an expansion of the expandable body; and a sheath ring circumferentially disposed about the at least one delivery cannula and the expandable body proximally adjacent to the plication region.

Independent claim 33 is not anticipated by Chow, because Chow does not disclose an apparatus including a sheath ring circumferentially disposed about a delivery cannula and an expandable body proximally adjacent to a plication region. The Patent Office cites Figure 3C of Chow as disclosing such a sheath ring. Figures 3B and 3C of Chow show needle 46 in a retracted and an extended position, respectively. Needle 46 is within delivery lumen 40. Referring to Figures 2A and 2B of Chow, delivery lumen 40 is defined by distal section 42 and proximal section 44. Distal section 42 is adhered to a proximal taper and possibly working length of balloon 20. See, column 5, lines 6-20.

> In one embodiment, as shown in FIG. 2B, delivery lumen 40 includes a bend region 50 at which distal section 42 of delivery lumen 40 is capable of bending (or generally rotating) about a pivotal point 51 with respect to proximal section 44. For example, to accomplish the pivotal movement, distal section 42 of delivery lumen 40 is in contact with proximal taper wall 36 of balloon 20

(FIG. 1A). Accordingly, in response to the inflation of balloon 20, section 42 moves relative to section 44 to form bend region 50.

Col. 5, lines 16-27. Chow does not describe a sheath ring disposed about delivery lumen 40 and balloon 20 or a sheath ring proximally adjacent a plication region such as pivotal point 51.

Perhaps the Patent Office is equating elongated catheter body 12 that extends from a proximal portion of catheter assembly 10 to a point proximal to pivotal point 50 with a sheath ring. Applicant does not believe, however, that catheter body 12 may constitute a sheath ring as that term is used in the Application. In addition, Chow does not describe that catheter body 12 is circumferentially disposed about delivery lumen 40 and balloon 20.

Claims 34-38, 42-43 and 45-46 depend from claim 33 and contain all the limitations of that claim. For at least the reasons stated with respect to claim 33, claims 34-38, 42-43 and 45-46 are not anticipated by Chow.

Independent claim 63 describes an apparatus including a first cannula body and a second cannula body comprising a superelastic material coupled to the first cannula body wherein the first cannula body and the second cannula body define a continuous lumen there through. To the extent that the Patent Office reads claims 63 to describe the first cannula body and the second cannula body as the same cannula body, Applicant amends claim 63 to describe that the second cannula body is different from the first cannula body. Examples of apparatuses within the scope of claim 63 are described in the Application beginning at paragraph 0082 and shown in Figs. 11-15. Representatively, Fig. 11 shows an embodiment of a distal portion of needle 47 that includes proximal section 110 of a material having sufficient column strength to make needle 47 pushable in the vasculature without buckling. An example of a suitable material is a stainless steel hypotube. Distal section 115 of needle 47 may be a superelastic material with a relatively high degree of bending stress, such as a nickel-titanium alloy. A pressure resistant connection is made between proximal section 110 and distal section 115 to define the single lumen therethrough.

Independent claim 63 is not anticipated by Chow, because Chow does not describe an apparatus including a first cannula body and a different second cannula body comprising a superelastic material, wherein the first cannula body and the second cannula body define a

continuous lumen therethrough. Chow appears silent on the makeup of, for example, its needle 46.

Claim 65 depends from claim 64 and therefore includes all the limitations of that claim. For at least the reasons stated with respect to claim 63, claim 65 is not anticipated by Chow.

Independent claim 92 describes a method including positioning a catheter assembly comprising at least one needle delivery device in a delivery cannula having an exit end; maintaining a prescribed orientation of the at least one delivery device at a proximal end; and maintaining a prescribed orientation of that at least one needle delivery device at a distal end. Independent claim 92 is not anticipated by Chow, because Chow does not describe maintaining a method that includes maintaining a prescribed orientation of a needle delivery device at a proximal end and maintaining a prescribed orientation of the needle delivery device at a distal end. Chow describes using a needle lock or a mechanical stop to secure a position of needle 46 in its catheter assembly. See col. 5, line 45 through col. 6, line 22. However, these position devices do not describe maintaining an orientation. It is appreciated that, for example, a needle may rotate in the device of Chow and thus be at a desired position but oriented improperly.

Claims 93-95 depend from claim 92 and therefore contain all the limitations of that claim. For at least the reason stated with respect to claim 92, claims 93-95 are not anticipated by Chow.

Applicant respectfully request that the Patent Office withdraw the rejection to claims 33-38, 42-43, 45-46, 63, 65 and 92-95 under 35 U.S.C. § 102(e).

B. 35 U.S.C. § 103(a): Rejection of claims 1-3, 5-8, 11-12, 17-19, 21-24 & 27-28

The Patent Office rejects claims 1-3, 5-8, 11-12, 17-19, 21-24 and 27-28 under 35 U.S.C. § 103(a) as obvious over Chow in view of U.S. Patent No. 6,770,053 of Scarfone, et al. (Scarfone). At the time the invention described in any of the rejected claims was made, Chow and the claimed invention were owned by Advanced Cardiovascular Systems, Inc. for subject to an obligation of assignment to the same. Accordingly, under 35 U.S.C. § 103(c), Chow shall not preclude patentability of the rejected claims.

Applicant respectfully request that the Patent Office withdraw the rejection to claims 1-3, 5-8, 11-12, 17-19, 21-24 and 27-28 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

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